REMARKS

Claims 1-7, 9-13, and 15-31 appear in this application for the Examiner's review and consideration, including new claim 31, which is fully supported by the originally filed specification, drawings, and claims.

Claims 1-6, 9, 10, 12, 13, 16-20, 22-28, and 30 were rejected under 35 U.S.C. § 102(b) as anticipated by Wardlaw. Also, claims 7, 11, 15, 21, and 29 were rejected under 35 U.S.C. §103(a) as obvious over Schluter in view of Tanaka.

The Office Action includes a remark that the term, "jet injector," is capable of being read on any standard hypodermic syringe. The basis for this remark is drawn from independent definitions from the dictionary for each of the terms, "jet" and "injector," defined separately. This is an improper construction of the actual term that is used, however, namely "jet injector," which is a term of art that is not merely a collection of the meaning of two independent words.

A person having ordinary skill in the art at the time of the application would have understood that a "jet injector" and "jet injection" define a particular type injector and injection that is different than a standard hypodermic injector/injection. As explained previously, it is well known in the art that a jet injector injects a medicament by creating a high speed jet of the medicament that penetrates the tissue of the patient as a jet to a significant distance beyond the end of the injector. This is different than a standard hypodermic injector, which merely deposits the medicament in a bolus around the needle tip.

Some jet injectors are called needle-assisted jet-injectors because then use a needle to penetrate the patient tissue by a short distance, and the energy created in the jet is used to fire the medicament significantly deeper into the tissue. Again, this would have been understood by one of ordinary skill in the art as being very different, and requiring a different structure, than for a standard hypodermic injection.

It is also known that jet injectors require certain components to generate the short duration, high-power firing stroke to generate sufficient pressure to drive the fluid out in a sufficiently powerful jet. These components include, for instance, a higher-powered energy source to drive the plunger with sufficiently elevated force when the injector is fired and carefully dimensioned and configured jet nozzle to efficiently form the high speed jet that can penetrate the tissue beyond the depth of the needle tip. Due to the high speed and pressure requirements for jet injectors, they are not powered by

pressing directly on a plunger by hand or by the soft springs that power auto-injectors, which are known to be automated versions of hypodermic injectors.

Consequently, the definition assumed for "jet injection" taken by combining the definitions of the two words independently is not what would be understood by a person having ordinary skill in the art, and is not what should be used for comparing the claims to the prior art.

As stated in the office action, each of the references applied in the rejections are for hypodermic syringes. None of them teach or suggest using a jet injector as properly defined. Wardlaw discloses that the teaching is of an "automatic hypodermic syringe." (*E.g.,* Wardlaw abstract.)

Schluter discloses a traditional hypodermic injection that is automated. While it states that it uses a high speed discharge, this is not a teaching or suggestion of a discharge that is sufficiently high speed or in a configuration that it could be considered a jet injection. The patent explains that the high speed is desired for rapid and reliable penetration of tissue parts having pain receptors (*e.g.,* Schluter 1:50-51), but still, the injection is traditional and the teaching is for automating this traditional injection to be used by an unskilled person (*e.g.,* Schluter 1:27-28). At most, this teaching provides using an injection speed that is on the fast side for standard hypodermic injections.

There is also no teaching or suggestion of modifying Schluter to provide a true jet injector. Additionally, the embodiments disclosed would likely be inoperable if they were to be modified to use the high injection forces of a jet injector. Each embodiment uses a needle that is freely placed within the ampoule, with a long needle length that would tend to buckle or seriously come out of alignment if subjected to the high compressive force that would be required. For this reason, one of ordinary skill in the art would be taught away from using higher injection forces than would be used for a fast hypodermic injection.

Finally, Tanaka also does not teach or suggest a jet injector. Consequently, there is no teaching or suggestion in Wardlaw or in any combination of Schluter and Tanaka of the claimed jet injector, and the claims are thus neither anticipated nor obvious over the references.

It is also noted that claims 28 and 31 define that the needle is in fixed association with the second end of the tube. This is contrary to the structures disclosed in Wardlaw and Schluter, in which the needles are specifically intended to be movable since

it is an important part of both of these references that the needle be retractable. Thus, claims 28 and 31 are also patentably distinct from these references.

In view of the foregoing, the entire application is now believed to be in condition for allowance, early notice of which would be appreciated. Should the Examiner not agree, then a personal or telephonic interview is respectfully requested to discuss any remaining issues in an effort to expedite the allowance of this application.

Respectfully submitted,

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for: E. Bradley Gould (Reg. No. 41,792)

WINSTON & STRAWN LLP
CUSTOMER NO. 28765

(212) 294-6610